

# What's Your Compliance IQ?

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## HIPAA News

The 2022 Cyber Threat mid-year report has been released & reports a 23% decrease in attempted ransomware attacks globally with the lowest number in 6-22 in 23 months.

While ransomware attacks are down overall, there was a 328% increase in the healthcare industry. Despite the global downturn, the year-to-date ransomware figures are still higher than in 2017, 2018, & 2019.

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A recent survey indicated 70% of respondents felt knowledgeable about cybersecurity yet the average person lands on a suspicious online site or social media account 6.5 times a day. Bad cyber hygiene & poor password practices are still commonplace. These bad cyber practices should be a concern to employers if associates are lax about

personal security despite knowing the risks of identity theft & fraud.

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HIPAA does not have a private "right of action." This means an individual cannot file a claim against a covered entity or business associate to enforce HIPAA or seek damages in response to a HIPAA violation. The sole remedy of an aggrieved individual is to file a complaint with the US DHHS Office of Civil Rights (OCR) or, more recently, with a state Attorney General.

The risk of a lawsuit while not common, poses significant risk management & liability concerns for any entity subject to HIPAA. A lawsuit risk is most pertinent to HIPAA violations that may cause financial, reputational or other harm to a party.

Hypothetical examples of suits:

- Inappropriate disclosure of medical records in response to a subpoena causing a former patient to lose custody of a child.
- Inappropriate disclosure of a child's medical records to an estranged parent when failing to verify that estranged parent's authority to get such records.
- Inappropriate use of hospital records by staff which causes severe embarrassment & distress to certain patients.

All facilities should be sure safeguards are in place to prevent the likelihood of inappropriate disclosures that may lead to a patient filing a lawsuit.

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A recent survey confirmed patients are concerned about the inability to ensure PHI remains confidential.. The AMA is highly concerned PHI is increasingly vulnerable.

## Compliance News

OIG has published its semi-annual report outlining the accomplishments of the fraud & abuse control program 10-1-21 through 3-31-22. \$1.14 B is expected in audit recoveries as well as 320 criminal actions, 320 civil actions, & 1043 exclusions.

Clinical laboratories figured prominently but not the usual finger pointing this time. While several of the most significant findings involved laboratory testing, the focus was on the impact of COVID-19 on testing. COVID-19 testing drove a 4% increase of Medicare Part B spending on lab tests despite a significant decrease in COVID-19 testing.

While acknowledging legitimate reasons increased genetic tests performed, payment for these tests & labs receiving more than \$1M for

performing these tests, these areas of increase indicate areas of possible concern such as excessive genetic testing & fraud.

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According to the Medicare Claims Processing Manual, consultations are paid under the physician fee schedule if they:

- Are requested by the patient's attending physician,
- Relate to a test result lying outside the clinically significant normal range per the patient's condition,
- Result in a written narrative report in the patient's medical record &
- Require the exercise of medical judgment by the consultant doctor

The new consult codes are only related to clinical laboratory services & must be differentiated from anatomic pathology services.

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A proposed rule was published by CMS 7-22-22 proposing a 20% across the board increase to existing CLIA fees. New fees proposed:

- Follow up surveys to confirm correction of deficiencies
- Review & approval of testing when a new testing specialty or subspecialty is added
- Compliant survey when findings are substantiated
- Desk reviews to ensure successful lab PT testing
- Issuing revised or replacement certificates

Will charge one time \$25 fee for Certificate of Waiver certificate; increase user fee every 2 years based on Consumer Price Index-Urban (CPI-U) to account for inflation, if needed, to meet CLIA program obligations.

# Safety

The Association of Public Health Laboratories (APHL) has issued a statement urging U.S. laboratories to enhance biosafety practices by implementing routine risk assessments, identifying best practices & standardized training, developing consensus standards & guidelines & improving reporting of exposure events.

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Like Covid-19, the unknowns about the Monkeypox virus are creating new laboratory safety concerns. Laboratorians who work with monkeypox patient samples must use Standard Precautions with no extra safety precautions or PPE needed per the CDC. If specimens are to be transported, staff must be

educated to package & ship Category B specimens.

Waste from the current strain of virus can be managed as regulated medical waste. Soiled laundry or lab coats, etc., should be bagged at the point of use. Staff should stay vigilant for any new threats or safety issues related to monkeypox.

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Since 10% formaldehyde is not flammable, there is no limit to how much can be stored in a specific area but an appropriate spill kit must be nearby.

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If an associate reacts to gloves provided by the facility, he/she should be evaluated by employee health. Vinyl

gloves do not provide sufficient protection even is marked "medical" gloves.

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Paraffin waste is know to contain xylene & should be disposed of as hazardous waste; the amount of xylene is small so it does not need to be stored inside a flammable cabinet.

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Phlebotomists do not have to wear lab coats to draw blood, but if a risk assessment indicates one is needed, it must be worn. Those performing both blood collection & preparation must wear one during specimen processing & it must be removed prior to working with a patient.

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# Miscellaneous

CMS has published a final rule to update the 1992 Proficiency Testing (PT) & referral requirements under CLIA. It addresses & updates current analytes & new technologies. It finalizes regulations for laboratories performing moderate & high complexity testing & indicates those voluntarily participating in PT for waived tests are subject to compliance; will be effective 2 years after final rule is published. A fact sheet is available at [CMS Fact Sheet - CLIA PT Changes](#).

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ACLA scored a victory July 15 when the DC Circuit Court ruled the 2016 PAMA Rule is indeed "arbitrary & capricious" because it does not reasonably explain the agency's use of NPIs to identify lab revenue. CMS "failed to consider an important aspect of the problem" addressed by the PAMA legislation, namely hospital lab pricing.

The bad news is the court refused to strike down the Rule or order CMS to go back & recalculate the PAMA rates.

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Congress has introduced legislation (Saving Access to Laboratory Services Act) requiring CMS to use a more statistically reliable representative sample of lab test prices to determine the Clinical Lab Fee Schedule (CLFS) reimbursement rates & would increase the time between price reporting from 3 to 4 years. The bill is bipartisan & could empower Congress to pass the bill (SALSA).

# Fun Spot

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"I started to get suspicious when I was playing a game online and my score was the same as my Social Security number."

### July Puzzle Answer:

One-if you put in one, it will not be an empty container.

### August Puzzle:

I'm tall when I am young & short when I am old. What am I?

### Trivia:

- Flamingos are pink because of their diet—algae, shrimp, and crustaceans.
- A wolf can smell its prey almost 2 miles away.
- It takes a sloth 2 weeks to digest a meal.
- Rhinoceros horns--made of hair.

- Only Maine borders only one other state.
- Alcohol can be advertised on U.S. TV only if it is not consumed in the ad—a FCC regulation
- Apples float because of their high volume of air (25%).
- Graveyards are attached to a church while cemeteries are stand-alone.
- There is a city named Rome on every continent.
- High heels were originally invented for men—during the reign of King Louis, heels indicated men were wealthy.